UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,622	01/14/2005	Takeshi Hagio	59150-8030	2017

22918 7590 11/27/2009

PERKINS COIE LLP
P.O. BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com
skempe@perkinscoie.com

Office Action Summary	Application No.	Applicant(s)	
	10/521,622	HAGIO ET AL.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,6,10-27,30-48 and 71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,6,10-27,30-48 and 71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 27, 2009 has been entered.

Claims 1, 4, 6, 10-27, 30-48, and 71 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because the recitation "the step of holding the cell under the pressure different from the atmospheric pressure" lacks antecedent basis. Furthermore, the claim recites "the conditions capable of inducing electroporation" which lacks antecedent basis since parent claim 1 instead refers to "conditions to induce electroporation."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 6, 10-27, 30-48, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmukler (US 5,173,158) in view of Gutierrez-Armenta et al. (US 2002/0046416) and Dev et al. (US 5,859,327).

Schmukler teaches a method of electroporation wherein cells are trapped into pores in a film with diameters smaller than the diameters of the cells, and an electric field is applied to cause electroporation of the trapped cells (column 1, line 60 through column 2, line 3). The device of Figure 1 can be used to practice the invention, wherein there is an insulating film 20 with pores (column 2, lines 65-66). The cells are placed into portion 35 of the container 10 (column 3, lines 2-3). The cells can be trapped into the pores by pressure such as hydrostatic pressure head from a regulated pressure source or a vacuum source (column 3, lines 20-26). Clearly the pressure applied to the cells must be different from atmospheric pressure. Thereafter, a low voltage pulse is applied which causes electroporation of the cells (column 3, lines 27-34).

It is noted that "when the pressure gradient across the film is negative, or decreases from a positive value, the trapped first type of cells will pull in material, such as genetic material (DNA)..." from portion 36 (column 3, lines 44-47). Thus, the container 10 holding the cells (portion 35) and the nucleic acids (portion 36) is depressurized.

Schmukler differs from the claimed invention in that it does not expressly disclose that the pressure in the container is reduced by about 0.096 MPa from the atmospheric pressure, as required by claims 1 and 27. Nevertheless, the selection of a specific suitable pressure, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Schmukler teaches regulation of pressure applied (column 3, lines 20-26).

Furthermore, Schmukler differs from the claimed invention in that it does not expressly disclose that the cell treated is a plant cell of the types recited in instant claims 10-26 wherein the steps can be performed on a seed, and that the treated plant cell differentiates/grows/multiplies and/or yields a plant which may not contain a somaclonal variation. Moreover, there is no disclosure in Schmukler that the voltage pulse applied to the cell is of 10 V/cm to 200 V/cm, which is applied to the cell and the nucleic acid in at least two directions.

Gutierrez-Armenta et al. discloses that cell growth may be controlled by administering DNA to a cell, and that the DNA may be administered by electroporation of plant seed cells with DNA (page 2, paragraph [0015]).

Dev et al. teaches "a method for producing a genetically modified plant by introducing a polynucleotide to an intact plant or plant cell(s) via electroporation, in the absence of cell wall-degrading enzymes" (abstract). The "plant cell" may be an intact cell of a seed (column 4, lines

15-17), wherein the recitation "intact" signifies that the cell wall is undamaged or untreated (column 4, lines 20-22). The method can be applied to monocotyledonous plants such as corn, wheat, rice, and dicotyledonous plants such as tomato, rapeseed, soybeans, and cabbage (column 6, lines 15-25). Moreover, Dev et al. indicates that "one of skill in the art could determine the appropriate parameters for the leaf type used" (column 8, lines 62-63). For instance, a voltage of 40-50 V/cm for electroporation, which is within the range recited in instant claim 6, is deemed suitable for "soft and thin" leaves (column 8, lines 63-65).

At the time the invention was made, it would have been obvious to have practiced the invention on plant cells, which can be contained in seeds, to produce plants which may not contain a somaclonal variation. One of ordinary skill in the art would have been motivated to do this since electroporation has been found to be suitable for administering DNA to plant seed cells, and therefore, there would have been a reasonable expectation of success in transferring nucleic acid into plant cells to produce a plant by the methods of Schmukler which uses electroporation for nucleic acid transfer into cells. Additionally, there would have been a reasonable expectation of success in transferring nucleic acids into cells of plants of the types recited in the instant claims to yield the predictable result of producing these plants.

Also, the selection of a specific suitable voltage pulse and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill. Also, Dev et al. demonstrates that the skilled artisan would determine the appropriate parameters for the leaf type used, and Dev et al. teaches that electroporation applied at a voltage of 40-50 V/cm, which is within the range recited in instant claim 6, is deemed suitable for the introduction of a polynucleotide to "soft and thin" leaves.

Moreover, Dev et al. also provides further support for administering DNA into cells of plants of the types recited in the instant claims by electroporation.

A holding of obviousness is clearly required.

Claims 1, 4, 6, 10-27, 30-48, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dev et al. in view of Porter et al. (US 2,932,128).

Dev et al. teaches "a method for producing a genetically modified plant by introducing a polynucleotide to an intact plant or plant cell(s) via electroporation, in the absence of cell wall-degrading enzymes" (abstract). The "plant cell" may be an intact cell of a seed (column 4, lines 15-17), wherein the recitation "intact" signifies that the cell wall is undamaged or untreated (column 4, lines 20-22). The method can be applied to monocotyledonous plants such as corn, wheat, rice, and dicotyledonous plants such as tomato, rapeseed, soybeans, and cabbage (column 6, lines 15-25). Moreover, Dev et al. indicates that "one of skill in the art could determine the appropriate parameters for the leaf type used" (column 8, lines 62-63). For instance, a voltage of 40-50 V/cm for electroporation, which is within the range recited in instant claim 6, is deemed suitable for "soft and thin" leaves (column 8, lines 63-65). Note that the cells can be placed in a cuvette with the plasmid DNA for electroporation (column 12, lines 29-40).

Dev et al. differs from the claimed invention in that it does not disclose that when the plant cell (such as a seed) is with the polynucleotide in a container (such as a cuvette), the container is depressurized to about 0.096 MPa below the atmospheric pressure, prior to putting the seed and the nucleic acid under conditions to induce electroporation.

Porter et al. discloses the inoculation of seeds under conditions of reduced pressure with particulate matter (column 1, lines 17-20). The particulate matter can be bacteria, and the seeds are subjected to reduced pressure while in contact with a liquid suspension of the particulate matter (column 2, lines 9-12). The seeds obtained through the process are intact (column 2, lines 33-36 and 47-49). Moreover, the extent to which the pressure is reduced in the inoculation step may vary considerably (column 2, lines 53-54). For instance, the treatment can be performed under a reduced pressure of about 1.1 inches of mercury (column 2, line 70 through column 3, line 2). A pressure of 1.1 inches of mercury is about 0.0037 MPa. Given that atmospheric pressure, 1 atm, is about 0.10 MPa, a pressure reduced by about 0.096 MPa from the atmospheric pressure is about 0.004 MPa. Therefore, Porter et al. teaches a pressure that meets the pressure limitation of instant claims 1 and 27.

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have included in the Dev invention a step of depressurizing the container holding the plant cell and polynucleotide prior to or during the electroporation step, when the plant cell is a seed. One of ordinary skill in the art would have been motivated to do this since the step of depressurization of a container holding a plant cell in a liquid suspension of particulate matter results in the inoculation of the seed with particulate matter. Given that particulate matter can enter the seed through depressurization, the seed can be inoculated with matter as small as a nucleic acid. Clearly depressurization would have contributed to introducing polynucleotides into seeds, thus improving the efficiency of the Dev invention. As a pressure of about 0.0037 MPa is suitable for delivering particulate material into a seed, it would have been obvious to have used such a pressure in delivering polynucleotides into seeds. Moreover, the

selection of a suitable pressure would have been a matter of routine experimentation, especially considering that Porter et al. indicates that "the extent to which the pressure is reduced in the inoculation step of this process may vary considerably" (column 2, lines 53-54). Thus, instant claims 1, 4, 10-16, 18-22, 27, 30-36, 38-42, 47, 48, and 71 are rendered obvious.

Additionally, there would have been a reasonable expectation of success in transferring nucleic acids into seeds of plants other than those indicated in the Dev invention to yield the predictable result of inoculating such seeds with polynucleotides. Thus, claims 17, 23-26, 37, and 43-46 are rendered obvious.

Also, the selection of a specific suitable voltage pulse and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Dev et al. teaches that the skilled artisan would determine the appropriate parameters for the leaf type used. Moreover, Dev et al. teaches that electroporation applied at a voltage of 40-50 V/cm, which is within the range recited in instant claim 6, is deemed suitable for the introduction of a polynucleotide into "soft and thin" leaves. Therefore, appropriate parameters for different seeds would also have been determined by the skilled artisan, and a voltage of 40-50 V/cm would have been a suitable starting point for routine experimentation for the selection of a specific voltage pulse. Thus, instant claim 6 is rendered obvious.

Response to Arguments

Applicant's arguments filed July 27, 2009, have been fully considered but they are not persuasive. The applicant asserts that Schmukler and Dev fail to teach or suggest that the plant

cell having an intact cell wall and contained within a seed is transformed by electroporation and depressurization. As pointed out, though Schmukler does not specifically indicate the cell type as claimed, Dev indicates that electroporation can be suitable for introducing a polynucleotide to an instant plant or plant cell, where the plant cell may be an intact cell of a seed. Dev indicates that "...a seed comprising multiple plant cells capable of regeneration into a whole plant is included in the definition of a plant cell."

The applicant also asserts that Schmukler fails to teach that the seed is placed within a container that is depressurized. However, Figure 1 of Schmukler shows that the cells are indeed placed into a container which is depressurized as the hydrostatic pressure head can be from a vacuum source (column 3, lines 20-23) and there can be a negative pressure gradient across the film (column 3, lines 44-47).

Finally, the applicant argues that it would be understood by those skilled in the art that the method of Schmukler, when applied to plant seeds containing many cells, would likely result in the cells contained within the seed being compressed, reducing spaces between cells, and thereby inhibiting nucleic acid containing buffer solution from entering said spaces between cells. However, the applicant has not provided evidence to support these assertions. As pointed out in MPEP 2145, section I, "The arguments of counsel cannot take the place of evidence in the record."

Therefore, the claims remain rejected over Schmukler in view of Gutierrez-Armenta et al. and Dev et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef